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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,322	RIGBY, LARRY	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/24/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS filed 11/24/2003.

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific deterrent agents, does not reasonably provide enablement for all deterrent agents including all irritating agents, all central nervous system effecting agents, all gastrointestinal system effecting agents, all cardiac effecting agents, all respiratory system effecting agents, all bowel effecting agents, all palate effective agents, all sleep inducing agents, and all smell effecting agents. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is transdermal drug delivery system comprising formulation comprising abusable drug and deterrent agent.

The breadth of the claims: The claims are very broad. The claims encompass all the drugs and chemicals that have effects on all the body systems including those having therapeutic effects, bittering effect, irritating effect, emetic effects, etc.

The state of the prior art: The state of the art recognized the effect of emetics and nauseating agents, bittering agents as well as agents having disgusting taste in protecting of human against abusing transdermal devices containing abusable drugs (US 7,011,843, US 2003/0064099, US 2003/0068370, US 2003/0068371, US 2003/0068375, US 2003/068392, US 2003/0124185, US 2003/0064122). The art does not recognize the effect of all drugs and chemicals that effect all the body systems to

deter from abusing the transdermal devices comprising abusable drugs as encompassed by the scope of the present claims.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on all central nervous system effecting agents, all gastrointestinal system effecting agents, all cardiac effecting agents, all respiratory system effecting agents, all bowel effecting agents, all palate effective agents, all sleep inducing agents, and all smell effecting agents that can be included in the transdermal device that deliver abusable drugs in order to deter from abuse. Some of the central nervous system effecting agents may provide synergistic effect. Some of the drugs may provide unwanted harmful side effects such as cardiovascular effecting drugs may cause bradycardia, hypotension or hypertension, etc. The specification disclosed and enabled emetics disclosed in example 5, droperidol as central nervous system effecting agent, capsaicin as irritant agent and berberine as bittering agent. The specification has not enabled all the drugs and chemicals encompassed by the scope of the claims as deterrent agents to protect from abuse of abusable drugs. It is not obvious from the disclosure of specific deterrent agents including emetics, droperidol, berberine, and capsaicin if all the other drugs and chemicals encompassed by the scope of the claims will work. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other

appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result". The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to all central nervous system effecting agents, all gastrointestinal system effecting agents, all cardiac effecting agents, all respiratory system effecting agents, all bowel effecting agents, all palate effective agents, all sleep inducing agents, and all smell effecting agents that have safe deterring effect from abusable drugs makes practicing the claimed invention unpredictable in the terms of deterrent agents.

The presence or absence of working examples: The specification discloses and enables only emetics disclosed in example 5, droperidol as central nervous system effecting agent, capsaicin as irritant agent and berberine as bittering agent. No working examples to show the effect of other deterrent agents.

The quantity of experimentation necessary: The art and the specification demonstrate droperidol, specific emetics, nauseating and bittering agents for protection against abuse of abusable drugs present in transdermal devices. Therefor, the practitioner would turn to trial and error experimentation to practice the instant invention

to deter from abuse of transdermal devices containing abusable drugs without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

4. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The claims are drawn to "means for preventing the delivery of said deterrent into human skin". The specification gives no guidance to one of ordinary skill in the art regarding "means for preventing the delivery for said deterrent agent into human skin". The specification does not describe "means for preventing the delivery of said deterrent into human skin".

The expression "means for preventing the delivery of said deterrent into human skin" without partial or complete description of any "means" does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The functional language "means for preventing the delivery of said deterrent into human skin" recited without any correlation does not meet the written description requirement for the means for preventing the delivery of said deterrent into human skin as one of ordinary skill in the art could not recognize or understand the means from the mere recitation of the function because the means can be chemical means, mechanical means or structural means. Claims employing functional language at the point of

novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of means and applicants claimed expression represents only an invitation to experiment regarding possible means.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. *Vas-Cath Inc. v Mahurkar*, 19 USPQ 2d 1111. The invention is, for purpose of the "written description" inquiry, what ever is now claimed (see page 1117). The specification does not clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 116). One cannot describe what one has not conceived. See *Fiddes v Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class, the specification provided only bovine sequence.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-6, 11 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "means for preventing the delivery of said deterrent into human skin" in claim 1 does not set forth the metes and bounds of the claim. Recourse to the specification does not define the expression.

Regarding claim 4, 11 and 16, the expressions "central nervous system effecting agents", "gastrointestinal system effecting agents", "cardiac effecting agents", "respiratory system effecting agents", "bowel effecting agents", "palate effective agents", "sleep inducing agents", and "smell effecting agents" do not set forth the metes and bounds of the claim. Recourse to the specification does not define the expressions.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 4, 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by US 7,011,843 ('843).

US '843 discloses method for the protection of a human being against any health impairment as a result of ingestion of a transdermal therapeutic system (TTS) containing active ingredient that cause addiction, such a method comprises adding to said transdermal therapeutic system a substance being able to keep off a human being

from said ingestion (abstract). The transdermal device comprises the addictive drug and pharmacologically neutral non-interacting substance with disgusting taste, with irritating effect on the tongue and/or oral mucosa, or with the property of inducing nausea (col.2, lines 1-13). The substance can be applied as a film on top of the active substance containing layer, applied to the backing layer in a separate layer, or added to one or more layers of the TTS to safely achieve a further intensification of the effect of the denaturation (col.2, lines 25-29, 33-36, 58-60; col.3, lines 4-10). The addictive drugs include analgesic drug, tranquilizer and psychoactive (col.4, lines 30-33). The substance that deters from abuse includes quinine (col.4, line 3) that inherently has an emetic effect.

9. Claims 1-6, 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0064099 ('099).

US '099 discloses providing a dosage form comprising drug susceptible to abuse and effective amount of a aversive agent including bittering agent, irritating agent or gelling agent to impart bitter taste to an abuser upon administration of the dosage form after tampering (abstract; paragraphs 0030, 0031). The bittering agent provides bitter taste upon inhalation or oral administration (paragraph 0045). Example of aversive agent includes quinine (paragraph 0044) that inherently has emetic effect. The drug can be extracted from the dosage form by dissolution in a solvent (paragraphs 0052, 0055). The dosage form that can be abused is Duragesic that is transdermal delivery systems

for delivering fentanyl (paragraphs 0056, 0057, 0160, 0161). The aversive agent can be coated to prevent the release of the aversive agent unless tampered (paragraph 0065). The reference discloses that aversive agent the addictive drug can be separated within the transdermal device by a layer that becomes disrupted when the transdermal device is tampered with (paragraph 0167).

10. Claims 1-6, 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0068370 ('370).

US '370 discloses providing a dosage form comprising drug susceptible to abuse and effective amount of a aversive agent including bittering agent, irritating agent or gelling agent to impart bitter taste to an abuser upon administration of the dosage form after tampering (abstract; paragraph 0030, 0031). The bittering agent provides bitter taste upon inhalation or oral administration (paragraph 0045). Example of aversive agent includes quinine (paragraph 0044) that inherently has emetic effect. The drug can be extracted from the dosage form by dissolution in a solvent (paragraphs 0052, 0055). The dosage form that can be abused is Duragesic that is transdermal delivery systems for delivering fentanyl (paragraphs 0056, 0057, 0160, 0161). The aversive agent can be coated to prevent the release of the aversive agent unless tampered (paragraph 0065). The reference discloses that aversive agent the addictive drug can be separated within the transdermal device by a layer that becomes disrupted when the transdermal device is tampered with (paragraph 0167).

11. Claims 1-6, 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0068371 ('371).

US '371 discloses providing a dosage form comprising drug susceptible to abuse and effective amount of a aversive agent including bittering agent, irritating agent or gelling agent to impart bitter taste to an abuser upon administration of the dosage form after tampering (abstract; paragraph 0033, 0034). The bittering agent provides bitter taste upon inhalation or oral administration (paragraph 0049). Example of aversive agent includes quinine (paragraph 0048) that inherently has emetic effect. The drug can be extracted from the dosage form by dissolution in a solvent (paragraphs 0055, 0056). The dosage form that can be abused is Duragesic that is transdermal delivery systems for delivering fentanyl (paragraphs 0079, 0080, 0190, 0191). The aversive agent can be coated to prevent the release of the aversive agent unless tampered (paragraph 0089). The reference discloses that aversive agent the addictive drug can be separated within the transdermal device by a layer that becomes disrupted when the transdermal device is tampered with (paragraph 0196).

12. Claims 1-6, 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0068375 ('375).

US '375 discloses providing a dosage form comprising drug susceptible to abuse and effective amount of a aversive agent including bittering agent, irritating agent or gelling agent to impart bitter taste to an abuser upon administration of the dosage form after tampering (abstract; paragraph 0030, 0031). The bittering agent provides bitter

taste upon inhalation or oral administration (paragraph 0045). Example of aversive agent includes quinine (paragraph 0044) that inherently has emetic effect. The drug can be extracted from the dosage form by dissolution in a solvent (paragraphs 0052, 0055). The dosage form that can be abused is Duragesic that is transdermal delivery systems for delivering fentanyl (paragraphs 0056, 0057, 0160, 0161). The aversive agent can be coated to prevent the release of the aversive agent unless tampered (paragraph 0065). The reference discloses that aversive agent the addictive drug can be separated within the transdermal device by a layer that becomes disrupted when the transdermal device is tampered with (paragraph 0166).

13. Claims 1-6, 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0068392 ('392).

US '392 discloses providing a dosage form comprising drug susceptible to abuse and effective amount of a aversive agent including bittering agent, irritating agent or gelling agent to impart bitter taste to an abuser upon administration of the dosage form after tampering (abstract; paragraph 0033, 0034). The bittering agent provides bitter taste upon inhalation or oral administration (paragraph 0049). Example of aversive agent includes quinine (paragraph 0048) that inherently has emetic effect. The drug can be extracted from the dosage form by dissolution in a solvent (paragraphs 0056). The dosage form that can be abused is Duragesic that is transdermal delivery systems for delivering fentanyl (paragraphs 0079, 0080, 0184, 0185). The aversive agent can be coated to prevent the release of the aversive agent unless tampered (paragraph 0088).

The reference discloses that aversive agent the addictive drug can be separated within the transdermal device by a layer that becomes disrupted when the transdermal device is tampered with (paragraph 0190).

14. Claims 1-6, 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0124185 ('185).

US '185 discloses providing a dosage form comprising drug susceptible to abuse and effective amount of a aversive agent including bittering agent, irritating agent or gelling agent to impart bitter taste to an abuser upon administration of the dosage form after tampering (abstract; paragraph 0033, 0034). The bittering agent provides bitter taste upon inhalation or oral administration (paragraph 0049). Example of aversive agent includes quinine (paragraph 0048) that inherently has emetic effect. The drug can be extracted from the dosage form by dissolution in a solvent (paragraphs 0056). The dosage form that can be abused is Duragesic that is transdermal delivery systems for delivering fentanyl (paragraphs 0079, 0080, 0184, 0185). The aversive agent can be coated to prevent the release of the aversive agent unless tampered (paragraph 0088). The reference discloses that aversive agent the addictive drug can be separated within the transdermal device by a layer that becomes disrupted when the transdermal device is tampered with (paragraph 0190).

15. Claims 1, 2, 4, 6, 13, 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0064122 ('122).

US '122 discloses transdermal dosage form comprising opioid and irritating agent such as capsaicin to deter abuser from oral ingestion, intravenous injection or intranasal snorting of the dosage form by causing severe irritating effect when crushed, or dissolved (abstract, paragraphs 0012, 0027, 0028, 0032; table 1, claims 1-3). The capsaicin is included in the same matrix as opioid or in a separate matrix (claims 20-21). The deterring agent is encapsulated to cause irritation to the mucus membrane without causing lasting damage (paragraph 0015).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 3, 5, 10, and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over US '843.

The teachings of US '843 are discussed above.

US '843 does not teach fentanyl as the abusive drug as claimed in claims 3 and 10, the abusable drug has the potential to be abused by inhalation as claimed in claim 5, or the separating film that separates the active drug from the deterrent agent as claimed in claim 12.

US '843 teaches method for protection of children and addicts from improper oral application of active abusable substances contained in oral patches. The reference disclosed analgesics and tranquilizers as the active substances to be abused. Fentanyl is an analgesic. The reference disclosed that the method is suitable for any abusive drug or toxic substance. Therefore, the method disclosed by the reference can be used to protect from improper oral application of any addictive and non-addictive substance. The novelty of the present invention is not in the drug delivered by the transdermal device, but the inclusion of deterrent agent in the device. Therefore, the limitation of transdermal device to deliver fentanyl as claimed in claim 3 and 10 does not impart patentability to the claims, absent evidence o the contrary. Regarding claim 5, it is expected that the abuser would use the drug obtained or extracted from the transdermal device by the route that is known to provides euphoria, i.e. if the transdermal device comprises morphine the addict more likely to ingest the device or try to extract the drug for injection, while if the drug is cocaine the addict more likely to snort the drug in the device, and so on. Hence, the limitation of claim 5 that abusable drug has the potential to be abused by inhalation does not impart patentability to the claims, absent evidence to the contrary. The novelty of the present invention is not how the addict would intend to abuse the transdermal device, but the inclusion of deterrent in the device. Regarding the layer separating the active drug from the deterrent agent as claimed in claim 12, US '843 recognized the addition of the active drug and the deterrent in two separate layers to safely achieve the denaturation effect of the drug (col.2, lines 36-37), and it is expected that one having ordinary skill in the art would add a layer to separate the drug

from the deterrent agent for more safety. The presence of the separating layer does not impart patentability to the claim in absence of superior and unexpected results.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a method for protection of a human being against health impairment as a result of ingestion of a transdermal therapeutic system comprising abusable drug by adding a substance with disgusting taste, with irritating effect on the tongue and/or oral mucosa, or with the property of inducing nausea to the transdermal device as disclosed by US '843, and use the such transdermal device to deliver any abusable or toxic substance including fentanyl, motivated by the teaching of US '843 that such a device deters children and addicts from improper use of the drug, with reasonable expectation of having transdermal device comprises fentanyl and deterrent agent that protect children and adults from health impairment associated with improper ingestion of addictive or toxic drug. Additionally, one having ordinary skill in the art would have added a layer to separate drug from the deterrent within the transdermal device motivated by the desire of US '843 to keep the drug and the deterrent separated within the transdermal device to safely achieve the denaturation effect of the drug, with reasonable expectation of having a safe TTS comprising separating layer between the drug containing layer and the deterrent containing layer.

18. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over US '843 in view of any of US '099, US '370, US '371, US '375, US '392 or US '185.

The teachings of the references are discussed above.

However, US '843 does not teach a layer to separate the drug containing layer from the deterrent agent containing layer as claimed in claim 12 that is taught by each of US '099, US '370, US '371, US '375, US '392 and US '185.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a method for protection of a human being against health impairment as a result of ingestion of a transdermal therapeutic system comprising abusable drug by adding a deterrent substance with disgusting taste, with irritating effect on the tongue and/or oral mucosa, or with the property of inducing nausea to the transdermal device and include the addictive drug and the aversive agents in two separate layers as disclosed by US '843, and further insert a layer that separate the drug containing layer and the deterrent agent containing layer as disclosed by any of US '099, US '370, US '371, US '375, US '392 and US '185, motivated by the teaching of any of the references that such a layer becomes disrupted only when the transdermal device is tampered with, with reasonable expectation of having transdermal device comprising a separating layer between the drug containing layer and the deterrent containing layer that disrupts only when the device is tampered with to ensure safely achievement of denaturation of the addictive drug.

19. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '122, US '099, US '370, US '371, US '375, US '392 and US '185 in view of US '843.

The teachings of the references are discussed above.

However, US '122, US '099, US '370, US '371, US '375, US '392 and US '185 do not teach that the deterrent formulation is coated on the backing and the drug formulation on the other as claimed in claim 7, which is taught by US '843, or the deterrent formulation is coated on one side of the backing and the drug formulation is coated on the top of the deterrent formulation as claimed by claims 8-12, which is taught by US '843.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal dosage form comprising drug susceptible to abuse and effective amount of a aversive deterrent agent to impart bitter taste to an abuser upon administration of the dosage form after tampering as disclosed by any of US '122, US '099, US '370, US '371, US '375, US '392 and US '185, and provide deterrent formulation on one side the backing of the device and the addictive drug formulation on the other side of the backing or provide the deterrent formulation coated on one side of the backing and the drug formulation coated on the top of the deterrent formulation as disclosed by US '843, motivated by the desire of all of US '122, US '099, US '370, US '371, US '375, US '392 and US '185 to separate the deterrent agent from the abusive drug and motivated by the teaching of US '843 that such a structure safely achieve a further intensification of the effect of the denaturation, with reasonable expectation of having TTS comprising layer containing the drug susceptible to abuse applied on one side of the backing and another layer containing deterrent agent applied on the other side of the backing or having the deterrent containing layer coated on one side of the backing and the drug containing layer coated on the top of the

deterrent formulation to achieve safe effective denaturation when the device is tampered with.

20. Claims 3, 5, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '122.

The teachings of US '122 are discussed above.

US '122 does not teach fentanyl as the abusive drug as claimed in claims 3 and 15, the abusable drug has the potential to be abused by inhalation as claimed in claim 5, or the deterrent agent as an emetic as claimed in claim 17.

US '122 teaches transdermal dosage form comprising opioid and irritating agent such as capsaicin to deter abuser from oral ingestion, intravenous injection or intranasal snorting of the dosage form by causing severe irritating effect when crushed, or dissolved. Therefore, the transdermal dosage form disclosed by the reference can be used to deliver any addictive and non-addictive substance. The novelty of the present invention is not in the drug delivered by the transdermal device, but the inclusion of deterrent in the device. Therefore, the limitation of transdermal device to deliver fentanyl as claimed in claims 3 and 15 does not impart patentability to the claims, absent evidence o the contrary. With regard to claim 5, it is expected that the abuser would use the transdermal device or the drug extracted from the device by the route known to provides euphoria, i.e. if the transdermal device comprises morphine the addict more likely to ingest the device or try to extract the drug for injection, while if the drug is cocaine the addict more likely to snot the device, and so on. Hence, the limitation of

claim 5 that abusable drug has the potential to be abused by inhalation does not impart patentability to the claims, absent evidence to the contrary. The novelty of the present invention is not how the addict intends to abuse the transdermal device, but the inclusion of deterrent in the device. Regarding the deterrent agent is emetic substance, US '122 recognized the addition of deterrent substance that deters the abuser from crushing or dissolving pharmaceutical dosing forms for abusive snorting, injection or ingestion, and it is expected that one having ordinary skill in the art would have used any deterrent agents including bittering agent, nauseating agents or emetic agents specially when the drug is intended to be abused by ingestion. Hence, the use emetic substance as deterrent does not impart patentability to the claims, absent superior and unexpected results.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal dosage form comprising abusive drug and deterrent agent as disclosed by US '122, and use the such transdermal device to deliver any abusable or toxic substance including fentanyl and any deterrent including emetic, motivated by the teaching of US '122 that such a dosage form deters the abuser from crushing or dissolving pharmaceutical dosing forms for abusive snorting, injection or ingestion, with reasonable expectation of having transdermal device comprises fentanyl and deterrent agent that deters the abuser from crushing or dissolving pharmaceutical dosing forms for abusive snorting, injection or ingestion.

21. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '843 in view of US '122.

The teachings of references are discussed above.

However, US '843 does not teach encapsulation of the deterrent agent in the dosage form, which is disclosed by US '122.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a method for protection of a human being against health impairment as a result of ingestion of a transdermal therapeutic system comprising abusable drug by adding a deterrent substance with disgusting taste, with irritating effect on the tongue and/or oral mucosa, or with the property of inducing nausea to the transdermal device as disclosed by US '843, and further encapsulate the deterrent substance as disclosed by US '122, motivated by the teaching of US '122 that encapsulation causes irritation to the mucus membrane without causing lasting damage, with reasonable expectation of successfully deterring the addict from abusing the addictive drug without causing any damage to the abuser.

Claim Objections

22. Claim 6 is objected to because of the following informalities: the terms "injection.e" and "snortingl" are misspelled. Appropriate correction is required.

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2004/0228802 discloses drug formulation having reduced

abuse potential comprising bittering agent. US 2003/0091635 discloses opioid formulation with reduced abuse potential comprises sustained release delivery system.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali
ISIS GHALI
PATENT EXAMINER